AMENDMENT AND RESPONSE TO OFFICE ACTION AND PETITION FOR ONE-MONTH TIME EXTENSION U.S. Serial No. 10/607,010

REMARKS

Assignee and the undersigned attorney thank Examiner Shaffer for his review of this patent application and the indication that claims 4 and 20 contain allowable subject matter. Claims 6-15, 22, 26, and 27 have been withdrawn pursuant to an election of species requirement. Claims 1, 3-5, 16, 18, 25, 30, 31, and 33 are amended above, and new claims 34-40 are added. Assignee respectfully requests reconsideration of claims 1-3, 5, 16-19, 21, 23-25, and 28-33 and consideration of claims 34-40.

Claim Objections

In the Action, the Examiner objected to claim 3 because of the recitation of "relative" in the claim without any additional information. Claim 3 is amended above, and Assignee respectfully requests that the Examiner withdraw the objection in view of the amendment.

Claim Rejections

In the Action, the Examiner rejected claims 1-3, 5, 16-19, 21, 23, and 30-33 under 35 U.S.C. § 102(b) as being anticipated by PCT Publication No. WO 00/40163 to Faccioli et al. ("Faccioli"). The Examiner rejected claims 24, 25, 28, and 29 under 35 U.S.C. § 103(a) as being unpatentable over Faccioli in view of U.S. Patent No. 5,160,335 to Wagenknecht ("Wagenknecht").

Claims 1-3, 5, 16, and 17

Amended claim 1 recites:

An external fixation apparatus comprising:

a first member attachable to a first bone segment through pins; a second member attachable to the first member through a lockable ball joint, the second member comprising a stem directly adjacent and

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coupled to a pin clamp, wherein first and second ends of the stem may be translated transversely relative to a longitudinal axis of the stem; and

a pin clamp coupled to and rotatable about the second end of the

stem through a lockable joint, the pin clamp being attachable to a second bone

segment.

The Examiner asserts that Faccioli teaches each and every element of original claim 1.

However, Faccioli fails to teach or suggest each and every element of amended claim 1.

More particularly, Faccioli does not teach or suggest a stem directly adjacent to a pin clamp,

wherein first and second ends of the stem may be translated transversely relative a

longitudinal axis of the stem.

In the Action, the Examiner refers primarily to Figure 2B of Faccioli and the

associated description in explaining what the asserted teachings of Faccioli. The Examiner

likens proximal portion 3 of Faccioli to the "first member" recited in claim 1, central body 2

and device 1 to the recited "second member," and pin clamp 40 and 50 to the recited "pin

clamp." Assignee notes that reference numeral 1 refers to the entire device, not a component

of the *Faccioli*. Additionally, it appears that the Examiner's position is that central body 2

and stem 20 of Faccioli together form a "second member" as recited in original claim 1.

Amended claim 1 recites that the second member comprises "a stem directly adjacent

and coupled to a pin clamp, wherein first and second ends of the stem may be translated

transversely relative to a longitudinal axis of the stem." However, in Faccioli, the stem 20

that is directly adjacent the pin clamp 40, 50 does not have first and second ends that can

move in the manner recited in claim 1. The entire stem 20 may rotate relative to the central

body 2 via the ball joint shown in Fig. 2B of Faccioli, but Faccioli does not teach or suggest

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that both ends of stem 20 can be translated transversely relative to the stem's longitudinal

axis. Faccioli teaches nothing more than a solid one piece, two-pronged stem.

For the above reasons, the Examiner should withdraw the rejection of claim 1 as

anticipated by Faccioli, and claim 1 should be allowed.

Inasmuch as claims 2, 3, 5, 16, and 17 depend from and thereby include the

limitations of claim 1, claims 2, 3, 5, 16, and 17 should also be allowed for at least such

dependencies. Claims 5 and 16 are also allowable for at least the following additional

reasons.

Amended claim 5 recites a stem with a single prong at its second end (i.e., the end of

the stem that is coupled to the pin clamp). Faccioli only teaches a stem with two prongs.

Thus, Faccioli does not teach the additional limitation recited in claim 5, and claim 5 should

be allowed for this additional reason.

Amended claim 16 recites additional features of the lockable joint that couples the

stem and the pin clamp of claim 1. Among those additional recited features are (a) a shaft

extending transversely from the second end of the stem, the shaft including at least one

groove extending around at least a portion of a circumference of the shaft; and (b) a locator

pin of the pin clamp that is received within the at least one groove to releasably couple the

stem to the pin clamp. Faccioli fails to teach or suggest either of these additional limitations.

The Examiner asserts that pivot 35 of Faccioli teaches the recited shaft of claim 16.

However, pivot 35 does not extend transversely from stem 20, but rather pivot 35 is captured

within the two prongs 23, 24 of stem 20. The Examiner also asserts that pivot 35 includes a

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hole that extends through the radius of pivot 35 and receives a lockpin 37, and that this teaches the "at least one groove . . ." recited in claim 16. While pivot 35 of *Faccioli* includes a hole, it does not include a groove "extending around at least a portion of a circumference of the shaft" as recited in amended claim 16. Moreover, the lockpins 37 of *Faccioli* are for permanently securing pivot 35 between the two prongs 23, 24 of stem 20, and thus permanently securing the upper jaw 40 of the pin clamp to the stem. (*See Faccioli* at page 9.) There is no teaching or suggestion that lockpins 37 can or should "releasably couple the

For the above additional reasons, the Examiner should withdraw the rejection of claim 16 as anticipated by *Faccioli*, and claim 16 should be allowed.

Claims 18, 19, 21, 23, and 24

Amended claim 18 recites:

stem and the pin clamp" as recited in claim 16.

An external fixation apparatus comprising:

- a first member attachable to a first bone segment through pins:
- a second member attachable to the first member through a lockable joint, the second member including a shaft extending transversely from a distal end of the second member with at least one groove extending around at least a portion of a circumference of the shaft; and
- a pin clamp attachable to a second bone segment and releasably coupled to and rotatable about the second member, the pin clamp comprising:
- a first jaw and a second jaw, the first jaw including a hole that receives the shaft;
- a locator pin that is received within the at least one groove of the shaft to releasably couple the second member and the pin clamp; and
- a first bolt that passes through openings in the first and second jaws such that tightening of the first bolt interferes with the shaft and locks rotation of the pin clamp about the second member.

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The Examiner asserts that Faccioli teaches each and every element of original claim 18.

However, Faccioli fails to teach or suggest each and every element of amended claim 18.

More particularly, Faccioli does not teach or suggest "the second member including a shaft

extending transversely from a distal end of the second member with at least one groove

extending around at least a portion of a circumference of the shaft," as recited in claim 18.

Additionally, Faccioli does not teach or suggest a pin clamp "releasably coupled to" a

second member or "a locator pin that is received within the at least one groove of the shaft to

releasably couple the second member and the pin clamp."

The Examiner asserts that pivot 35 of Faccioli teaches the recited shaft of claim 18.

However, pivot 35 does not extend transversely from stem 20, but rather pivot 35 is captured

within the two prongs 23, 24 of stem 20. The Examiner also asserts that pivot 35 of Faccioli

includes a hole that extends through the radius of pivot 35 and receives a lock pin 37, and

that this teaches the "at least one groove . . ." recited in claim 18. While pivot 35 includes a

hole, it does not include a groove "extending around at least a portion of a circumference of

the shaft" as recited in amended claim 18. Moreover, the lockpins 37 of Faccioli are for

permanently securing pivot 35 between prongs 23, 24 of stem 20, and thus permanently

securing the upper jaw 40 of the pin clamp to the stem. (See Faccioli at page 9.) There is no

teaching or suggestion that lockpins 37 can or should "releasably couple the stem and the pin

clamp" as recited in claim 18, and, in fact, pin clamp 40, 50 and stem 20 of Faccioli are not

releasably coupled.

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For these reasons, the Examiner should withdraw the rejection of claim 18 as anticipated by *Faccioli*, and claim 18 should be allowed. Inasmuch as claims 19, 21, 23, and 24 depend from and thereby include the limitations of claim 18, claims 19, 21, 23, and 24 should also be allowed for at least such dependencies.

Claims 25, 28, and 29

Amended claim 25 recites:

In an external fixation system for attaching pins or wires to at least one bone segment, the system comprising:

an external fixation device; and a pin clamp comprising:

a first jaw and a second jaw;

biasing elements received within openings in the first and second jaws;

first and second bolts that extend through the openings in the first and second jaws, compressing the biasing elements and holding the first and second jaws together;

a hole in the first jaw configured to receive a shaft that extends transversely from an end of an external fixation device, the shaft having at least one groove extending around at least a portion of a circumference of the external fixation device;

a locator pin that is received within the at least one groove of the shaft to releasably couple the external fixation device and the pin clamp; and

a third bolt that passes through openings in the first and second jaws such that sufficient tightening of the third bolt interferes with the shaft and locks rotation of the pin clamp about the external fixation device.

The Examiner asserts that original claim 25 is obvious in view of *Faccioli* combined with *Wagenknecht*. However, for reasons similar to those described above with respect to claim 18, the cited references, either alone or in combination, fail to teach or suggest a hole in the first jaw of the pin clamp that is "configured to receive a shaft that extends transversely from an end of the external fixation device, the shaft having at least one groove extending around

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at least a portion of a circumference of the external fixation device" or "a locator pin that is

received within the at least one groove of the shaft to releasably couple the external fixation

device and the pin clamp."

Thus, the Examiner should withdraw the rejection of claim 25 as obvious in view of

the combination of Faccioli and Wagenknecht, and claim 25 should be allowed. Inasmuch as

claims 28 and 29 depend from and thereby include the limitations of claim 25, claims 28 and

29 should also be allowed for at least such dependencies.

Claims 30-33

Amended claim 30 recites:

A method of treating a skeletal condition or injury using an external

fixation apparatus, the method comprising:

(a) fixing a first member to a first side of a fracture with upper bone pins, the first member being coupled to a second member through

a lockable ball joint;

(b) fixing a pin clamp to a second side of the fracture with

lower bone pins, the pin clamp being coupled to and rotatable about a stem of the second member through a second lockable joint, the stem being directly

adjacent to the pin clamp and comprising first and second ends; and

(c) adjusting a first end and a second end of the stem

transversely relative a longitudinal axis of the stem to precisely reduce the

fracture.

For reasons similar to those described above with respect to apparatus claim 1, Faccioli does

not teach or suggest each and every element of amended method claim 30. More

specifically, Faccioli does not teach or suggest adjusting a first end and a second end of the

stem transversely relative a longitudinal axis of the stem to precisely reduce the fracture,

where the stem is directly adjacent to and coupled to the pin clamp.

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For these reasons, the Examiner should withdraw the rejection of claim 30 as

anticipated by Faccioli, and claim 30 should be allowed. Inasmuch as claims 31-33 depend

from and thereby include the limitations of claim 30, claims 31-33 should also be allowed for

at least such dependencies.

Claims 34-40

New claims 34-40 are presented for examination, and no new matter has been added.

Conclusion

The foregoing is submitted as a full and complete response to the Action mailed

January 11, 2006. Assignee submits that claims 1-5, 16-21, 23-25, and 28-40 are in

condition for allowance, and notice of allowance is respectfully requested. The preceding

arguments in favor of patentability are advanced without prejudice to other bases of

patentability. If the Examiner believes there are any issues that can be resolved via a

telephone conference, or there are any informalities that can be corrected by an Examiner's

amendment, please call Geoffrey Gavin at (404) 815-6046.

Other than the fee for the one-month extension of time and the fee for new claims 34-

40, the undersigned attorney believes no other fees are due; however, the Commissioner is

authorized to debit deposit account no. 11-0855 to the extent necessary if other fees are due.

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Respectfully submitted,

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